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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WILDER, CYNTHIA B	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/830,976	HAYDOCK ET AL.	
	Examiner	Art Unit	
	Cynthia B. Wilder, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8, 10-40, 48-54, 56-57, 59-74, 76-90* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 10-40, 48-54, 56-57, 59-74, 76-90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

FINAL ACTION

1. Applicant's amendment filed July 12, 2005 is acknowledged and has been entered. Claim 1, 6, 7, 15, 25, 50, 53, 56 and 64 have been amended. Claims 9, 41-47, 55, 58, 75 and 91 have been canceled. Claims 1-8, 10-40, 48-54, 56-57, 59-74, 76-90 are pending. All of the arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons discussed below. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims.

This action is made FINAL

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Previous Rejections

The prior art rejections under 35 USC 102 are maintained and discussed below. The prior art rejections under 35 USC 103 are maintained and discussed below.

Claim Rejections - 35 USC § 102

3. Once again, claims 1-8, 10-19, 22-30, 38-40, 48-57, 59-69, 71, 73-74, 76-80, 88 and 89 are rejected under 35 U.S.C. 102(b) as being anticipated by Gustafson et al (US 5,478,527, December 26, 1995). The preceding claims are sufficiently broad to encompass the following reference cited below. It is further noted that the instant prior art should have been cited in the previous Office Action. The examiner regrets any inadvertent inconvenience. Regarding claim 1-8, 10, 15, 22-25, 49-57, 59, 64 and 73-75, Gustafson et al teach a method for detecting a target analyte comprising contacting an insoluble support with a first reagent; removing the solid

support from contact wit h the first reagent solution and contacting the solid support with a second reagent solution; wherein cross-contamination of the second reagent solution by the first reagent solution is reduced by coating the solid support with a non-stick material prior to contacting the solid support with the first reagent solution. Gustafson et al teach wherein the solid support is contacted with one or more intermediate solutions, wherein said intermediate solutions are one or more wash solutions. Gustafson et al further teach wherein the solid support is removed from containers containing the reagents, said container are selected from the group consisting of microwells, plates or a dipstick. Gustafson et al teach that the solid support is a silicon chip or wafer or microwell plate and further wherein the solid support comprises a capture regent which specifically binds to a target analyte (see col. 7, beginning at line 5 to col. 9, lines 4-26).

Regarding claim 11-12, 14, 18-19, 28-30, 38-40, 48-49, 60-61, 63, 68, 69, 73, 78-80, 88 and 89, Gustafson et al teach the method of claim 1 and 11, wherein a first reagent is TWEEN 20 or TRITON and the second reagent solution comprises a substrate which produces a detectable product when contacted with an enzyme linked to a signal reagent. This encompasses binding pairs such, as e.g., biotin, avidin, antibody, antibody fragment selected from the group consisting of Fab, Fab', or F(ab')2 fragments, hybrid antibody, protein A, protein G, chelating agent, enzyme, enzyme inhibitor, protein receptor, nucleotide hybridizing agent, antigen, hapten, lectin or a bacteria, virus, spore, parasite, yeast or fragment thereof or combinations thereof (col. 7, beginning at line 5 to col. 9, lines 4-26).

Regarding claim 13, 16, 17, 48, 62, 65-67, Gustafson et al teach the method of claim 1, wherein the non-stick coating material is silane or polysilane polymers (col. 9, lines 4-26).

Regarding claim 21, 71 Gustafson et al teach wherein the capture reagent is attached to the solid support prior to the contacting the test sample with the solid support (col. 7, beginning at line 5 to col. 9, lines 4-26).

Regarding claim 26, 27, 76, 77, Gustafson et al teach wherein the capture reagents is covalently attached or non-covalently attached to the solid support (col. 7, lines 16 to col. 8, line 11). Therefore, Gustafson et al meets the limitation of the claims recited above.

Applicant's Traversal

4. Applicant traverses the rejections on the following grounds: Applicant states that summarizes the passages cited by the Examiner and asserts that the passage as recited at col. 9, lines 11-19 does not teach or suggest any particular way to "treat" the polymer to render the surface non-binding to proteinaceous materials. Applicant states that based on this passage alone, the practitioner might well be at a loss to how to treat a polymer to render it non-binding to proteins. Applicant states that read after and in light of the present disclosure, it is understandable if the action reads this passage as suggesting treating the polymers with a non-stick coating, but as of this point in the text, Gustafson has not actually taught any particular way to treat the polymer to render them non-binding, including the use of a non-stick coating. Applicant cites the passages concerning treatment of "silicon dioxide surface with silanes" and states that this sentence is used by the action to show that Gustafson anticipates coating the polymers with a non-stick coating and specifically the use of silanes of polysilanes polymers. Applicant states that there are several problems with this analysis. Applicant asserts that the sentence does refer to applying silanes to the silicon dioxide, not the dipstick surface. The

paragraph in which the sentence appears is a description of Figure 3, which shows a cross-section of a dipstick having mounted thereon a plurality of insoluble supports having a diffraction grating design of binding reagent on it. By contrast, Gustafson refers consistently to silicon dioxide as the transparent layer of the diffraction gratings. Thus, the critical sentence relied on by the action relates to treatment of the diffraction grating surface rather than the dipstick, which does not appear to be anywhere stated to be silicon dioxide. Applicant further asserts that the sentence refers to "the silanes". Applicant reminds the examiner that "silane" is a specific compound, while "silanes" refer to derivatives of that compound, some of which are sticky and some of which are non-sticky. Applicant notes that a word search of the Gustafson specification reveals that every other mention of silanes in the Gustafson specification refers to aminosilanes used specifically to make the surface of the transparent layer of the diffraction grating able to bind protein. Applicant summarizes col. 5, lines 27-30. Applicant states under ordinary rules of construction, therefore, the sentence of Gustafson relied on by the Action refers to aminosilanes, which render surfaces capable of binding proteins, rather than the non-sticky compound known as silane. Applicant reminds the Examiner that a patent can anticipate only that which it enables, and the critical sentence arguably enabling the person skill to practice the claims currently under examination is bested garbled and at worst teaches away from using non-stick coatings. Applicant states that the reference does not anticipate the use of non-stick coating on dipsticks, microtiter plates or beads. Finally applicant states that the Gustafson does not teach or suggest the use of non-stick coating on non-optically flat surface such as beads, membranes, or particles and cannot anticipate them.

Examiner's Response

5. All of the arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons that follows: In response to Applicant's arguments that Gustafson et al does not teach any particular way to "treat" the polymer to render the surface non-binding to proteinaceous material, it is noted that the courts have established that during patent examination the pending claims must be interpreted as broadly as their terms reasonably allow (*In re Zletz, 893 F.2d 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).* In this case, the claims as broadly written do not teach or suggest how cross-contamination is reduced by coating a surface with a non-stick material. There is nothing in the claims or specification which would suggest that any non-stick coating on a surface or that the components within a nonstick material is responsible for reducing cross-contamination. Likewise the claims are not limited in such a way that render the solid support non-binding to proteins. In fact, the specification and claims teach wherein a capture agent, which may be a protein-like compound or enzyme, is bound to the solid support. This teaching supports the fact that the solid support can bind to proteinaceous materials. Thus, one would be at a loss as to how to "treat" the surface of the instant invention given the claims as broadly written. In regards to Applicant's arguments, that the reference applies silanes to the silicon dioxide of a diffraction grating, not a dipstick surface, while it is noted that the Examiner agrees that the silanes are coated on silicon dioxide layers, it is further noted that no limiting structure or definition is provided in the specification or claims for "a dipstick", or "a microtiter plate" or "a membrane", or "a particle". In fact, these supports can have many different meanings and structures in the art. Additionally, the claims do not limit the support to a particular surface, but rather broadly identifies what the structure may encompass. Thus the

claimed structures as Applicant argues and identifies as solid supports, are not clear. In this case, the Examiner maintains that Gustafson meets the limitation by teaching a solid support comprising a flat plate of transparent glass that is coated with a non-stick material mounted onto a dipstick, hence a solid support.

In regards to Applicant's arguments concerning silanes as a specific compound as noted in the amendment filed on October 25, 2002, it is noted that the claims as written do not distinguish between silane compounds but only recites "wherein the coating is selected from the group consisting of silane...". Additionally, while the Examiner agrees that the reference of Gustafson teaches at col. 5 that "preferably the silicon dioxide is treated with a suitable silane to increase its protein binding", it is noted that the specification teaches wherein the solid support is bound to a capture agent, hence binding to a protein. Likewise, the references does not exclude other silane compounds from being used in the teachings of Gustafson because at col. 9, Gustafson et al teaches that the solid support (dipstick) is made to minimize non-specific binding during the binding assays procedures. Col. 9, lines 11-19 of the Gustafson further teaches that the solid support may be treated to render the surface non-binding to proteinaceous material and further states that silanes can be applied to the silicon dioxide surface in a vapor phase, which clearly suggest that silane compounds non-binding to proteins are also utilized. Furthermore, neither the claims nor specification teach or suggest that proteins cannot bind to the coated solid support of the instant invention. There is no indication anywhere that such teachings are excluded. Hence the Examiner maintains that Gustafson meets the instant invention as written. In regards to Applicant's arguments that the reference relies on "aminosilanes", it is noted that no teaching is found in Gustafson that suggest that the "silanes" are "aminosilanes". Even moreso,

the claims do not exclude "aminosilanes" as being encompassed by the instant invention but only recite "silanes" which constitutes any compound associated with silanes. In regards to Applicant's arguments that the reference does not teach or suggest the use of non-stick coating on on-optically flat surfaces such as beads, membranes or particles, the Examiner reiterates that the specification does not provide any limiting structural features or definitions of a non-optically flat surface. While, one would assume a "bead" to be a round surface, what constitutes a "membrane" or "particle"? Is a membrane not a "flat surface"? Given the claimed invention as broadly written, the Examiner maintains that the reference of Gustafson anticipates the instant invention.

Claim Rejections - 35 USC § 102

6. Once again, claims 1, 10, 13-17, 20-22, 26, 27 29, 31-36, 38-40, 48-50, 62-67, 70-72, 81-87 and 90 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilding et al (US 5,587,128, December 24, 1996). Regarding claims 1, 10, 13-17, 20-22 29, 31-32, 48-50, 62, 64-67, 70-72, Wilding et al teach a method of reducing cross-contamination of an assay reagent solution, the method comprising: contacting a solid support with a first reagent solution; and contacting the solid support with a second reagent solution; contacting the solid support with a second reagent solution by the first reagent solution is reduced by coating the solid support with a non-stick material prior to or subsequent to contacting the solid support with the first reagent solution, wherein the non-stick coating material is selected from the group consisting of silane, dimethlychlorosilane, hexamethyldisilazane or trimethylchlorosilane (col. 5, lines 27-39). Wilding et al teach wherein the solid support comprises a capture reagent that binds to a target

analyte, wherein said capture reagent is attached to the solid support prior to or simultaneously with or after contacting the test sample with the solid support and wherein the target analyte comprises a polynucleotide (e.g., DNA or RNA) and wherein the capture reagent comprises a polynucleotide probe or antibody (col. 9, lines 15-53 and col. 19, lines 38-46).

Regarding claims 26 and 27, Wilding et al teach that composition may be attached to the solid support covalently or non-covalently (col. 5, lines 45-48).

Regarding claim 33 and 63, Wilding et al teach wherein the signal reagent comprises a detectable label attached to an oligonucleotide, which hybridizes to the polynucleotide (col. 20, lines 13-23).

Regarding claims 35, 36, 85 and 86, Wilding et al teach wherein the polynucleotide is amplified prior to contacting the sample with the capture reagent, wherein said amplified procedure is selected from the group consisting of polymerase chain reaction, ligase chain reaction, strand displacement amplification (col. 6, lines 40-67)

Regarding claims 38-40, 83, 84, 88-90 Wilding et al teach wherein the capture agent comprises and antibody which binds to the target analyte or an oligonucleotide which binds to the target analyte. Wilding et al additionally teach wherein the signal reagent may be an antibody which binds to the target analyte and wherein the signal reagent comprises a detectable label which may be attached to an oligonucleotide or antibody (col. 19, line 38 to col. 20, line 29). Therefore, Wilding et al meet the limitations of the claims recited above.

Applicant's Traversal

7. Applicant traverse the rejection on the following ground: Applicant summarizes the teaching of Wilding and states that Wilding relates to the use of "mesoscale flow systems" that

are referred to as "small, mass produced, typically one use devices (sometimes referred to herein as "chips") for conducting a reaction". Applicant states that the "chips" comprises a substrate engineered to contain a reaction chamber in which the reaction can occur, and inlet and outlet ports to introduce and remove reagents. Applicant states that the surface of the reaction chamber can be coated to diminish inhibition of an amplification reaction. Applicant states that Wilding is concerned only with possible inhibition of the amplification reaction by the walls of the substrate chamber. Applicant contends that it does not recognize the problem of carry over of reagents nor provide a solution to that problem. Applicant states that while Wilding mentions magnetic beads can be provided along with the mesoscale flow system to bind to amplified polynucleotides, there is no recognition that reagents carry over on the beads would pose a problem and of course no suggestion to coat the beads to solve the yet unrecognized problem. Applicant states that none of the embodiments of the claims as amended are taught or suggested by Wilding's treatment of self-contained chips. Applicant respectfully request the rejections be withdrawn.

Examiner's Response

8. All of the arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons that follow: In regards to Applicant's arguments that , Wilding only teaches the use of a coating in the context of a one-piece chip in which to conduct reactions, it is noted that the claims as written only require the use of a coating in the context of a one-piece chip in which to conduct a reaction in the recitation of the solid support being a "dipstick , a microtiter plate, a bead, a membrane or a particle". Neither the specification nor claims provide any structural limitations or definitions for the solid supports recited in the claims. In fact, the

structure as taught by Wilding can be considered to be a microtiter plate as required by the claims (see Figures 1-6). In regards to Applicant's arguments, that Wilding does not recognize the problem of carry over of reagents nor provide a solution to that problem, it is noted that the claims as written also does not appear to recognize the problem of carry over of reagents nor provide a solution to that problem. The claims only require that a solid support be coated with a non-stick material which is taught by Wilding. How this non-stick material reduces the problem of carry over is not clearly recited in the instant claims. While it is noted that Applicant mentions Wilding lack of teaching of coating beads as a means of not recognizing the problem of carry over, it is noted that beads are not the only solid support of the instant invention. If the solid support is a membrane or microtiter plate or particle or dipstick as recited in the claims, then how does the claims recognize the argued problem of carry-over when it only requires the solid support to be coated with a non-stick material as taught by Wilding? Clearly, the claims do not sufficiently support Applicant's arguments. The rejections noted under 35 USC 102 are maintained.

Claim Rejections - 35 USC § 103

9. Once again, claims 37 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gustafson et al as previously applied above in view of Van Ness (Nucleic Acids Research, Vol. 19, No. 19, pages 5143-5151, 1991). Regarding claim 37, Gustafson et al teach a method for reducing cross-contamination and detecting an analyte in a sample using a solid support as previously discussed above. Gustafson teach wherein in the method, the solid support is contacted with a denaturant wherein said denaturant is a detergent. Gustafson et al differs from the instant invention in that the reference does not teach wherein the denaturant is a chaotropic

solution selected from the group consisting of guanidine, sodium thiocyanate, urea, and lithium tetrachloroacetate. In a general teaching, Van Ness discloses the advantages of using chaotropic solution in nucleic acid diagnostic assays which are in a sandwich assay format (utilization of solid support). Van Ness teaches that chaotroptic solution, such as e.g., lithium tichloroacetate, guanidinium chloride, guanidinium thiocyanate, sodium thiocyanate, rubidium trichloroacetate, sodium perchlorate, potassium iodide or cesium trifluoroacetate (page 5144, first paragraph of col. 1), are significantly advantageous in terms of reducing background in a sandwich assay format (pages 5148 to page 5149, entire section entitled "Reduction of background in a sandwich Assay format using TCA-based hybridization solution"; see also introduction on page 5143). Therefore, in view of the foregoing, one of ordinary skill in the art would have been motivated to have modified the method of Gustafson et al to encompass the use of a chaotropic agent such as guanidine or lithium tetrachloracetate as the denaturant instead of a detergent as used by Gustafson in the detection method for the advantages of reducing background as taught by Van Ness.

Applicant's traversal and Examiner's Response

10. Applicant traverses the rejection on the following grounds: Applicant states that the independent claims have been amended to be free of Gustafson. Applicant asserts that since the obviousness rejection relies on combining Van Ness with Gustafson, and since the claims have been amended to be fee of Gustafson, it is respectfully submitted that the claims as amended are also free of the combination with Van Ness. Applicant request withdrawal of the rejections in light of the amendments filed therein.

11. All of the arguments have been thoroughly reviewed and considered and not found persuasive for the reasons that follow: In response to Applicant's arguments that the independent claims have been amendment to be free of Gustafson, it is noted that the amended does not obviate the prior art rejection in view of Gustafson for the reasons noted above at #5. Accordingly, the obviousness rejection based on the combination of Gustafson in view of Van Ness is maintained.

Conclusion

12. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to cynthia.wilder@uspto.gov. Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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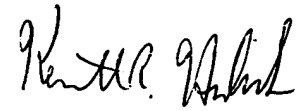

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

9/19/05